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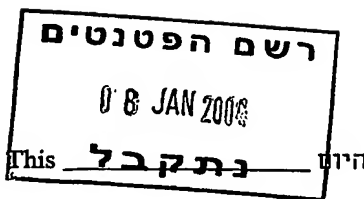
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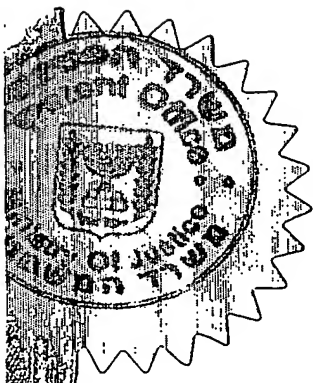
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PATENTS LAW, 5727-1967

בקשה לפטנט  
Application for Patent

מספר: Number	152486
תאריך: Date	25-10-2002
הוקדם/נדחה Ante/Post-dated	

אני, (שם המבקש, מענו – ולגבי גוף מאוגד – מקום התאגדותו)  
I (Name and address of applicant, and, in case of a body corporate, place of incorporation)

MEIR EINI  
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ISRAEL

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(בעברית)  
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ALCOHOL-FREE COSMETIC AND PHARMACEUTICAL FOAM CARRIER

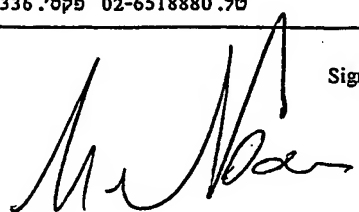
(באנגלית)  
(English)

הממציא(ים): דב תמרקין; מאיר עיני; מיכה פלד; דורון פרידמן

Inventor(s): Dov Tamarkin; Meir Eini; Micha Peled; Doron Friedman

hereby apply for a patent to be granted to me in respect thereof.

מבקש בזאת כי ינתן לי עליה פטנט.

* בקשת חלוקה - Application for Division	* בקשת פטנט מוסף Application for Patent of Addition	* דרישת דין קדימה Priority Claim		
* מבקשת פטנט from Application	* לבקשה / לפטנט To Patent/Appl.	מספר/סימן Number/Mark	תאריך Date	מדינת האיגוד Convention Country
No. _____ מס' Dated _____ מיום	No. _____ מס' Dated _____ מיום			
* יפוי כח: כללי/מיוחד – רצוף בזה / עוד יוגש P.O.A.: general / specific - attached / to be filed later - הוגש בענין _____ Has been filed in case _____				
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תכשיר קצף נטול אלכוהול לשימוש קוסמטי ורפואי

ALCOHOL-FREE COSMETIC AND PHARMACEUTICAL FOAM CARRIER

**Inventors:**

Dov Tamarkin

Meir Eini

Micha Peled

Doron Friedman

# ALCOHOL-FREE COSMETIC AND PHARMACEUTICAL FOAM CARRIER

## ABSTRACT

The invention relates to a alcohol-free cosmetic or pharmaceutical foam carrier composed of 0.1% to 10% by weight of a foam adjuvant agent, comprising a long chain fatty alcohol or long chain fatty acid, 25-75% by weight water and 25% to 75% by weight of a hydrophobic solvent. Said cosmetic or pharmaceutical foam carrier does not contain aliphatic alcohols, making it hypoallergic and non-drying. The alcohol-free foam carrier is suitable for inclusion of both water soluble and oil soluble active agents.

## DESCRIPTION

### FIELD OF THE INVENTION

The invention relates to a alcohol-free cosmetic or pharmaceutical foam carrier and its use. More specifically, a kind of cosmetic or pharmaceutical foam carrier, having excellent spreading properties. The alcohol-free foam carrier is suitable for inclusion of both water soluble and oil soluble active agents.

### BACKGROUND OF THE INVENTION

An important route of the administration of drug for treating disease is external, topical administration and the drug is absorbed through skin, mucous membrane or wound tissue. Nowadays, in the market, there are many kinds of pharmaceutical dosage forms to be used externally, but they have some disadvantages. For instance, when ointments containing vaseline as the carrier are applied to wounds, metabolic products and excreta from the wounds are not easily removed for the difficulty of passing through the carrier and to be drained away. The active drug dissolved in the carrier is difficult to pass through it to go into the wound tissue, so the efficacy of the drug is affected.

Therefore, in many cases, ointments and creams can not create an environment for promoting respiration of the wound tissue and it is not favorable to the normal respiration of the skin. Many groups of drugs, including, for example, antibiotic, anti-fungal, anti-inflammatory; anesthetic, analgesic, anti-allergic, corticosteroid, retinoid and anti-proliferative medications are preferably administered in hydrophobic media, e.g. vaseline. However, due to the undesirable consistency of vaseline and similar hydrophobic carriers, their use is limited. An additional disadvantage of vaseline-carrier products relates to the greasy feeling left following their topical application onto the skin, mucosal membranes and wounds. Besides vaseline, hydrophobic pharmaceutical carriers now in use include liquid paraffin, lanolin, beeswax, vegetable oil, glycerin

monostearate, higher alcohols, polyethylene glycol and some emulsifying agents, which also have undesirable flow properties.

Several hydrophobic liquids, e.g., mono- and poly-unsaturated oils from vegetable and marine sources, silicone oils, mineral oils, and liquid hydrophobic plant-derived oils are known for their therapeutic benefits when applied topically, yet, their application in liquid form is not practically acceptable and therefore, turning them into semi-solid, without altering their chemical composition is highly desirable. Oils also contain essential nutritional constituents, such as oil-soluble vitamins (e.g., vitamin A and vitamin E), minerals and other therapeutically beneficial constituents. Thus, such therapeutic oils which heretofore have been administered in liquid form cannot be applied by consumes in amounts sufficient to exert therapeutic affects, because of their flow properties. Another class of therapeutic oils includes mineral and silicon oils useful for the treatment of skin dehydration and other medical disorders, which oils are liquid at ambient temperature.

Other pharmaceutical active ingredients are water-soluble and require a water component in the carrier.

In cosmetics, semi-solid formulation can have many applications, as carriers of sunscreen compounds; oil-soluble and water-soluble plant extracts, particulate materials for scrubbing purposes and other active and non-active cosmetic ingredients.

Thus, the development of a new composition, having breakable foam consistency when extruded out of a container and liquid properties when applied onto the skin is advantageous.

US Pat. No. 6,126,920 teaches methods of treating various skin diseases, and in particular, scalp psoriasis, utilizing a foamable pharmaceutical composition comprising a corticosteroid active substance, a quick-break foaming agent, an aliphatic alcohol, water, a fatty alcohol, a surface active agent a propellant.

According to US Pat. No. 6,126,920, said composition contains an aliphatic alcohol, preferably in amounts of 40-90% w/w composition, more preferably 55-70% w/w, especially 57-59% w/w, said aliphatic alcohol is preferably chosen from methyl, ethyl, isopropyl and butyl alcohols, and mixtures of two or more thereof. Ethanol has been found to be particularly preferred.

However, such alcohols, and particularly methyl, ethyl and isopropyl alcohols are defatting agents and may cause skin to become dry and cracked. They penetrate your skin's protective barrier and break down intercellular matrix. In a recent publication by the American Academy of Dermatology (AAD), titled "Facing the Facts about Skin Care Products" it is stated that "Individuals with dry

skin should avoid astringents and any product with alcohol because they easily strip away moisture from the skin.” (see: [www.aad.org/PressReleases/FacingFacts.html](http://www.aad.org/PressReleases/FacingFacts.html)). Another AAD publication, titled “Sensitive About Your Skin?” it is advised to “Avoid solvents that penetrate the skin including, propylene glycol and ethanol.” (see: [www.aad.org/PressReleases/sensitive.html](http://www.aad.org/PressReleases/sensitive.html)). In further publication by AAD, rosacea patients are advised to avoid facial products such as soap, moisturizers, and sunscreens containing “alcohol or other irritating ingredients” (see: [www.aad.org/pamphlets/rosacea.html](http://www.aad.org/pamphlets/rosacea.html)).

Moreover, in several skin disorders, such aliphatic alcohols may worsen the condition. It is known, for example that excessive skin dryness can be a trigger for new psoriasis lesions and thus, skin drying agents, such as aliphatic alcohol should preferably be eliminated from psoriasis remedies. Likewise, alcohols can initiate inflammatory reaction in subjects with sensitive skin, and those who are rosacea prone. Hence, the presence of aliphatic alcohol in a therapeutic foam, as taught in US Pat. No. 6,126,920 is undesirable.

Furthermore, from reading US Pat. No. 6,126,920, it becomes obvious that no oil or any other hydrophobic solvent can be included in the composition therein. It is well known that in psoriasis, as well as many other skin disorders, compositions without oil are inferior in terms of their therapeutic effect and cosmetic acceptability.

US Pat. 6,423,323 teaches a foam skin cream, which does not contain PTFE. An optional ingredient according to US Pat. 6,423,323 is one or more refatting substances, which are oils, in preferable concentrations of 0.5 to 2%, if the product is to be used for normal skin; and 3 to 6% for dry skin. Further, according to US Pat. 6,423,323, the amount of refatting substance may be up to 20% by weight.

Thus, foam compositions for topical treatment, containing higher concentrations of oils, are still desirable.

A particularly desirable type of oil containing foam is such wherein all or part of the oil phase comprises silicone oil. Silicone oil is known for its skin protective features and its incorporation in topical products is beneficial. However, it is not obvious to produce silicone oil-based foams, since many silicone oils possess anti-foaming properties.

## DESCRIPTION OF THE INVENTION

We have developed an alcohol-free cosmetic or pharmaceutical foam carrier comprising a hydrophobic solvent, water, a foam adjuvant agent, a surface active agent and a water gelling agent, in the following amounts:

- hydrophobic solvent: 25-75% by weight
- water: 25-75% by weight
- foam adjuvant agent: 0.1% to 5% by weight
- surface active agent: 0.1% to 5% by weight
- water gelling agent: 0.1% to 5% by weight

Said cosmetic or pharmaceutical foam carrier does not contain aliphatic alcohols, making it hypoallergic and non-drying. The alcohol-free foam carrier is suitable for inclusion of both water-soluble and oil soluble active agents.

More preferably, the alcohol-free foam carrier comprising a hydrophobic solvent, water, a foam adjuvant agent, a surface active agent and a water gelling agent, in the following amounts:

- hydrophobic solvent: 25-50% by weight
- water: 25-75% by weight
- foam adjuvant agent: 0.4% to 1.5% by weight
- surface active agent: 0.1% to 1% by weight
- water gelling agent: 0.1% to 1% by weight

In a further preferred embodiment, the alcohol-free foam carrier comprising a silicone oil as the hydrophobic solvent, water, a foam adjuvant agent, a surface active agent and a water gelling agent, in the following amounts:

- silicone oil: 7.5-50% by weight
- water: 50-90% by weight
- foam adjuvant agent: 0.4% to 1.5% by weight
- surface active agent: 0.1% to 1% by weight
- water gelling agent: 0.1% to 1% by weight

We have further developed an alcohol-free cosmetic or pharmaceutical product, comprising said carrier and an active cosmetic or pharmaceutical ingredient, in a therapeutically effective concentration. Such product is intended for topical treatment of human and animal skin disorders.

Finally, we have identified cosmetic and medical disorders which are best treated using the alcohol-free foam carrier and the alcohol-free cosmetic or pharmaceutical product and demonstrated the advantages of such carrier and products, in comparison with currently available options.

Advantages: the foam over current options, include: (1) the foam is lightweight and thus, economical; (2) the foam includes active agent, both water soluble and oil soluble; (3) the foam is easily spreadable, allowing treatment of large areas such as the arms and the breast; and (4) due to its flow properties, it

spreads effectively into folds and wrinkles, providing uniform distribution of the active agent without the need of extensive rubbing and absorbs into the skin.

## DEFINITIONS

### Hydrophobic solvent

A **hydrophobic solvent** is typically liquid at ambient temperature, i.e., an oil. Preferred hydrophobic solvents are liquid oils from vegetable, marine or animal sources. By way of example, the unsaturated oil may be selected from the group consisting of olive, corn, soybean, canola, cottonseed, coconut, sesame, sunflower, borage seed, *syzigium aromaticum*, hempseed, herring, cod-liver, salmon, flaxseed, wheat germ and evening primrose oils and mixtures thereof, at any proportion.

A particularly preferred class of oils includes **polyunsaturated oils**, containing omega-3 and omega-6 fatty acids. Examples of such polyunsaturated fatty acids are linoleic and linolenic acid, gamma-linoleic acid (GLA), eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). Thus, in an especially preferred embodiment of the present invention said unsaturated oil contains at least 6% of an oil selected from omega-3 oil, omega-6 oil, and mixtures thereof.

Another particularly preferred class of oils are **essential oils**, which are considered "therapeutic oils", i.e., oils which contain active biologically occurring molecules and, upon topical application, exert a therapeutic effect. Examples of such oils are rosehip oil, which contain retinoids and is known to reduce acne and post-acne scars, tea tree oil, which possess antibacterial, antifungal and antiviral properties. Other examples of essential oils are basil, camphor, cardamom, carrot, citronella, clary sage, clove, cypress, frankincense, ginger, grapefruit, hyssop, jasmine, lavender, lemon, mandarin, marjoram, myrrh, neroli, nutmeg, petitgrain, sage, tangerine, vanilla, verbena, as well as any other therapeutically beneficial oil, known in the art of herbal medication.

Another preferred class of solvents includes mineral oils, silicone oils, and liquid hydrophobic plant-derived oils, which are known to possess therapeutic benefits when applied topically.

**Silicone oils** are particularly preferred, due to their known skin protective properties. These are preferably chosen from cyclic or linear polydimethylsiloxanes containing from about 3 to about 9, preferably from about 4 to about 5, silicon atoms. Other silicone oils may be also included, such as polyalkyl siloxanes, polyalkylaryl siloxanes and polyether siloxane copolymers (e.g. dimethicone copolyol). The polyalkyl siloxanes useful herein include, for example, polydimethyl siloxanes with viscosities of from about 5 to about 100,000 centistokes at 25° C, preferably, polydimethyl siloxanes having viscosities from about 10 to about 400 centistokes at 25° C.



A further preferred class of hydrophobic solvents may be selected from the group comprising isostearic acid derivatives, isopropyl palmitate, lanolin oil, diisopropyl dimerate, maleated soybean oil, octyl palmitate, isopropyl isostearate, cetyl lactate, cetyl ricinoleate, tocopheryl acetate, acetylated lanolin alcohol, cetyl acetate, glyceryl oleate, tocopheryl linoleate, wheat germ glycerides, arachidyl propionate, myristyl lactate, decyl oleate, propylene glycol ricinoleate, isopropyl lanolate, pentaerythrityl tetrastearate, neopentylglycol dicaprylate/dicaprate, hydrogenated coco-glycerides, isononyl isononanoate, isotridecyl isononanoate, myristal myristate.

The hydrophobic solvent of the present invention may comprise a mixture of the above hydrophobic solvents in any proportion, providing that the total amount is 25-75% by weight of the carrier mass. More preferably, the total amount is 25-60% by weight of the carrier mass.

### **Foam adjuvant agents**

Preferred foam adjuvant agents, according to the present invention include fatty alcohols having 15 or more carbons in their carbon chain, such as cetyl alcohol and stearyl alcohol (or mixtures thereof). Other examples of fatty alcohols are arachidyl alcohol (C20), behenyl alcohol (C22), 1-triacontanol (C30), as well as alcohols with longer carbon chains (up to C50). The concentration of the fatty alcohol, required to support the foam system is inversely related to the length of its carbon chains. Fatty alcohols, derived from beeswax, comprising a mixture of alcohols, a majority of which has at least 20 carbon atoms in their carbon chain, are especially well suited as foam adjuvant agents according to the present invention.

Another preferred class of foam adjuvant agents, according to the present invention, includes fatty acids having 16 or more carbons in their carbon chain, such as hexadecanoic acid (C16) stearic acid (C18), arachidic acid (C20), behenic acid (C22), octacosanoic acid (C28), as well as fatty acids with longer carbon chains (up to C50), or mixtures thereof.

Optionally, the carbon atom chain of the fatty alcohol or the fatty acid may have at least one double bond. A further class of foam adjuvant agent according to the present invention comprises a long chain fatty alcohol or fatty acid, wherein the carbon atom chain is branched. In an additional preferred class of foam adjuvant agents, the carbon chain of said fatty acid is substituted with a hydroxyl group, such as 12-hydroxy stearic acid.

The foam adjuvant agent of the present invention may comprise a mixture of fatty alcohols, fatty acids and hydroxy fatty acids and derivatives thereof in any proportion, providing that the total amount is 0.1% to 5% by weight of the carrier

mass. More preferably, the total amount is 0.4% - 2.5% by weight of the carrier mass.

An important superior property of said fatty alcohols and fatty acids is related to their therapeutic properties *per se*. Long chain saturated and mono unsaturated fatty alcohols, e.g., stearyl alcohol, ercyl alcohol, arachidyl alcohol and docosanol have been reported to possess antiviral, anti infective, anti-proliferative and anti-inflammatory properties (US Patent No. 4,874,794). Longer chain fatty alcohols, e.g., tetracosanol, hexacosanol, heptacosanol, octacosanol, triacontanol, etc. are also known for their metabolism modifying properties and tissue energizing properties. Long chain fatty acids have also been reported to possess anti-infective characteristics. Thus, the pharmaceutical or cosmetic carrier, containing the foam adjuvant agent of the present invention provides an extra therapeutic benefit in comparison with currently used vehicles, which are inert and non-active.

### **Surface active agents**

**Preferred surface active agents**, according to the present invention include any agent linking oil and water in the foam, by way of emulsification. Best foaming agents are anionic followed by amphoteric and non-ionic and poor foaming are the cationic.

The surface active agent is suitably selected from anionic, cationic, nonionic, zwitterionic, amphoteric and ampholytic surfactants, as well as mixtures of these surfactants. Such surfactants are well known to those skilled in the pharmaceutical and cosmetic formulation art. Nonlimiting examples of possible surfactants include sucrose esters, sorbitan esters, PEG esters or ethers of fatty chains, fatty alcohols or acids, mono or diglycerides, isoceteth-20, sodium methyl cocoyl taurate, sodium methyl oleoyl taurate, sodium lauryl sulfate, triethanolamine lauryl sulfate and betaines.

While any surface active agent may be used as surface active agent of the present invention, those having an HLB higher than 9 are preferred.

In a more preferred embodiment, the surface active agent is selected from the groups of non ionic surfactants, cationic surfactants, amphoteric and zwitterionic surfactants. Yet, in a most preferred embodiment is a non-ionic surfactant.

### **Water gelling agents**

**Preferred water gelling agents** that can be used in accordance with the present invention include for example, but are not limited to, naturally-occurring polymeric materials such as, locust bean gum, sodium alginate, sodium caseinate, egg albumin, gelatin agar, carrageenin gum sodium alginate, xanthan

gum, quince seed extract, tragacanth gum, starch, chemically modified starches and the like, semi-synthetic polymeric materials such as cellulose ethers (e.g. hydroxyethyl cellulose, methyl cellulose, carboxymethyl cellulose, hydroxy propylmethyl cellulose), polyvinylpyrrolidone, polyvinylalcohol, guar gum, hydroxypropyl guar gum, soluble starch, cationic celluloses, cationic guar and the like and synthetic polymeric materials such as carboxyvinyl polymers, polyvinylpyrrolidone, polyvinyl alcohol polyacrylic acid polymers, polymethacrylic acid polymers, polyvinyl acetate polymers, polyvinyl chloride polymers, polyvinylidene chloride polymers and the like.

Also useful herein are water gelling agents such as the acrylic acid/ethyl acrylate copolymers and the carboxyvinyl polymers sold, for example, by the B.F. Goodrich Company under the trademark of Carbopol Registered TM resins. These resins consist essentially of a colloiddally water-soluble polyalkenyl polyether crosslinked polymer of acrylic acid crosslinked with from 0.75% to 2.00% of a crosslinking agent such as polyallyl sucrose or polyallyl pentaerythritol. Examples include Carbopol 934, Carbopol 940, Carbopol 950, Carbopol 980, Carbopol 951 and Carbopol 981. Carbopol 934 is a water-soluble polymer of acrylic acid crosslinked with about 1% of a polyallyl ether of sucrose having an average of about 5.8 allyl groups for each sucrose molecule.

#### **“Alcohol free”**

Unlike the composition, disclosed in US Pat. No. 6,126,920, which contains an aliphatic alcohol, preferably in amounts of 40-90% w/w composition, more preferably 55-70% w/w, especially 57-59% w/w, said aliphatic alcohol is preferably chosen from methyl, ethyl, isopropyl and butyl alcohols, the composition of the present invention does not contain such amount alcohols. For the purpose of this application, the term “alcohol free” shall mean that the composition contains no more than 7.5% of any aliphatic alcohol, having one to six carbon atoms in their carbon backbone, or no more than 7.5% of any mixture of such aliphatic alcohols.

#### **Optional Ingredients**

The pharmaceutical or cosmetic foam carrier of the present invention may further optionally comprise a variety of pharmaceutical or cosmetic ingredients, which are added in order to fine-tune the consistency of the formulation, protect the formulation components from degradation and oxidation and bestow their cosmetic acceptability. Such excipients, may be selected, for example, from the group consisting of diglycerides, triglycerides, stabilizing agents, antioxidants, glycerol, flavoring, colorant and odorant agents and other formulation components, used in the art of pharmaceutical and cosmetic formulary. A pharmaceutical or cosmetic composition manufactured using the foam carrier according to the present invention is very easy to use. When applied onto the afflicted body surface of humans or animals, it is in a foam state, allowing free

application without spillage. Upon further application of a mechanical force, e.g., by rubbing the composition onto the body surface, it freely spreads on the surface and is rapidly absorbed.

### **Emollients**

A preferred class of optional ingredients is emollients. Suitable emollients for use are isostearic acid derivatives, isopropyl palmitate, lanolin oil, diisopropyl dimerate, maleated soybean oil, octyl palmitate, isopropyl isostearate, cetyl lactate, cetyl ricinoleate, tocopheryl acetate, acetylated lanolin alcohol, cetyl acetate, phenyl trimethicone, glyceryl oleate, tocopheryl linoleate, wheat germ glycerides, arachidyl propionate, myristyl lactate, decyl oleate, propylene glycol ricinoleate, isopropyl lanolate, pentaerythrityl tetrastearate, neopentylglycol dicaprylate/dicaprate, hydrogenated coco-glycerides, isononyl isononanoate, isotridecyl isononanoate, myristal myristate, triisocetyl citrate, cetyl alcohol, octyl dodecanol, oleyl alcohol, panthenol, lanolin alcohol, linoleic acid, linolenic acid, sucrose esters of fatty acids, octyl hydroxystearate and mixtures thereof. Examples of other suitable emollients can be found in the Cosmetic Bench Reference, pp. 1.19-1.22 (1996).

### **ACTIVE PHARMACEUTICAL AGENTS**

The active drugs may be a single drug or a combination of drugs that can be dissolved in said solvent. Therefore, they are usually hydrophobic. Examples of such drugs are antibiotic, antibacterial, antifungal, antiviral, antiinflammatory, anesthetic, analgesic, antiallergic, corticosteroid, retinoid and antiproliferative medications and mixtures thereof at any proportion. The concentration of said drugs may be adopted to exert a therapeutic effect on a disease when applied to an afflicted area.

#### **Antibacterial agents**

One important class of drugs is comprises antibacterial agents. It is well known that bacterial infections are involved in a variety of superficial disorders of the skin, eye, mucosal membrane, oral cavity, vagina and rectum. The antibacterial drug can be active against gram positive and gram-negative bacteria, aerobic bacteria and anaerobic ones

The antibacterial drugs can be selected from the group of chloramphenicol, tetracyclines, synthetic and semi-synthetic penicillins, beta-lactams, quinolones, fluoroquinolones, macrolide antibiotics, peptide antibiotics, cyclosporines and any combination thereof at a therapeutically effective concentration. Another group of antibacterial agents which is non-specific, comprises strong oxidants and free radical liberating compounds, such as hydrogen oxide, bleaching agents (e.g., sodium, calcium or magnesium hypochloride and the like) iodine, chlorohexidine and benzoyl peroxide.

Antibacterial compositions according to the present invention may be used to treat infections of the skin. An example of a very common skin infection is acne, which involve infestation of the sebaceous gland with *p. acnes*, as well *staphylococcus aureus* and *pseudomonas*. Various antibacterial agents have been utilized to treat acne, however, their efficacy is limited due to their low penetration into the hydrophobic environment of the sebaceous gland. The composition of the present invention, being hydrophobic would facilitate an enhanced rate of penetration. Furthermore, the intrinsic antibacterial and antiinflammatory effects of the foam adjuvant agents, i.e., fatty alcohols and acids, provides a combined effect that should result in a better therapeutic response to treatment.

The application of the composition of the present invention in other cases, such as cuts, wounds, burns and ulcers is beneficial both in the cure of the infection or in the protection of the skin from infection. In all such cases, the present formulation is easy to use, being in foam state when applied and becoming liquid instantly upon rubbing onto the skin.

While being useful in the prevention and treatment of infections, the foam of the present invention is also applicable for decontaminating areas, afflicted with bacterial warfare organisms, such as anthrax and smallpox.

The same advantage is expected when the composition of the present invention is topically applied to mucosal membranes, the oral cavity, the vagina and the rectum.

### **Anti-fungal agents**

Fungal infections are another object of treatment using the composition of the present invention. Superficial fungal infection of the skin is one of the commonest skin disease seen in general practice. Dermatophytosis is probably the most common superficial fungal infection of the skin. It is caused by a group of fungi which are capable of metabolizing the keratin of human epidermis, nails or hair. There are 3 genera of dermatophytes causing dermatophytosis i.e, *microsporum*, *trichophyton* and *epidermophyton*.

Candidiasis is an infection caused by the yeast like fungus *candida albicans* or occasionally other species of *candida*. Clinical syndromes of candidiasis include: (a) oral candidiasis (oral thrush); (b) candidiasis of the skin and genital mucous membrane; and (c) *candida paronychia*, which inflicts the nail.

The pharmaceutical composition may comprise an antifungal drug, which is active against dermatophytes and *candida*, selected from the group of azoles, diazoles, triazoles, miconazole, fluconazole, ketoconazole, clotrimazole, , itraconazole griseofulvin, ciclopirox, amorolfine, terbinafine, Amphotericin B, potassium iodide, flucytosine (5FC) and any combination thereof at a therapeutically effective concentration.

## Anti-viral agents

The composition of the present invention is particularly beneficial in the case of viral infections. Cold sores are caused by the herpes simplex Type 1 virus and are sometimes referred to as facial herpes. Mollusca are small viral growths that appear singly or in groups on the face, trunk, lower abdomen, pelvis, inner thighs, or penis. Shingles (herpes zoster), which usually only occurs once in a lifetime, appears as a rash (clusters of blisters with a red base). It is caused by the same virus responsible for chickenpox. Warts are a common, benign skin tumor caused by viral infection.

Viral infections are currently treated with various antiviral agents, as summarized in the following table:

Drug	Viruses	Chemical Type
Vidarabine	Herpesviruses	Nucleoside analogue
Acyclovir	Herpes simplex (HSV)	Nucleoside analogue
Gancyclovir	Cytomegalovirus (CMV)	Nucleoside analogue
Nucleoside-analog reverse transcriptase inhibitors (NRTI): AZT (Zidovudine), ddI (Didanosine), ddC (Zalcitabine), d4T (Stavudine), 3TC (Lamivudine)	Retroviruses (HIV)	Nucleoside analogue
Non-nucleoside reverse transcriptase inhibitors (NNRTI): Nevirapine, Delavirdine	Retroviruses (HIV)	Nucleoside analogue
Protease Inhibitors: Saquinavir, Ritonavir, Indinavir, Nelfinavir	HIV	Peptide analogue
Ribavirin	Broad spectrum: HCV, HSV, measles, mumps, Lassa fever	Triazole carboxamide
Amantadine / Rimantadine	Influenza A strains	Tricyclic amine
Interferons	Hepatitis B and C	Protein

Any of the above antiviral drugs, in a therapeutically effective concentration, can be incorporated in the foam composition of the present invention. The composition of the present invention, which comprises a hydrophobic solvent, would facilitate an enhanced rate of penetration and better topical distribution of any of the above listed antiviral drugs. Furthermore, the intrinsic antiviral effects of the foam adjuvant agents, i.e., fatty alcohols and acids, provides a combined effect that should result in a better therapeutic response to treatment.

### Antiinflammatory or antiallergic agents

Yet, according to another embodiment according to the present invention the drug is an antiinflammatory or antiallergic agent. Antiinflammatory or antiallergic agent can be selected from the group of corticosteroids, non-steroidal antiinflammatory drugs (NSAIDs), anti-histamines, immunosuppressants and any combination thereof at a therapeutically effective concentration. The following table provides a summary of currently available corticosteroid agent and their typical therapeutically effective concentration.

Potency	Compound	Formulation
Very high	Clobetasol propionate	Cream or ointment 0.05%
	Halobetasol propionate	Cream or ointment 0.05%**
High	Betamethasone dipropionate	Cream or ointment 0.05%
	Betamethasone valerate	Ointment 0.1%
	Fluocinolone acetonide	Cream 0.02%
	Halcinonide	Cream or ointment 0.1%
Medium	Betamethasone valerate	Cream 0.1%
	Fluocinolone acetonide	Cream or ointment 0.020%
	Hydrocortisone valerate	Cream or ointment 0.2%
	Triamcinolone acetonide	Cream, ointment, or lotion 0.1% or 0.020%
Low	Hydrocortisone	Cream, ointment, or lotion 1.0% or 2.5%

The concentrations of corticosteroid drugs, as presented in the above table are provided herein only as example, and any therapeutically effective concentration of such corticosteroids can be incorporated in the composition of the present invention.

Since all corticosteroid drugs are typically hydrophobic, the carrier of the present invention, comprising a hydrophobic solvent, is most suitable as a vehicle to facilitate an enhanced rate of penetration and better topical distribution of any of the above listed antiviral drugs. Furthermore, the intrinsic antiviral, antibacterial and antiinflammatory effects of the foam adjuvant agents, i.e., fatty alcohols and acids, provides a combined effect that should result in a better therapeutic response to treatment.

Psoriasis is a very common chronic skin disease, which may be the target of treatment using the composition of the present invention. It is marked by periodic flare-ups of sharply defined red patches covered by a silvery, flaky surface.

Corticosteroid ointments, greasy preparations containing little water, are commonly used for treating psoriasis. Their main disadvantage is in their sticky feeling, which remains so long after treatment is over. By contrast, the foam of the present invention, while comprising considerable concentration of an oil

(hydrophobic solvent), spread very easily throughout the afflicted area and absorbs into the skin without leaving any untoward sensation or look. Examples of other inflammatory disorders, which can be treated by the composition of the present invention, wherein the drug is a steroid are seborrheic dermatitis of the face and trunk, seborrheic blepharitis, contact dermatitis, stasis dermatitis (gravitational eczema; varicose eczema), exfoliative dermatitis (erythroderma), lichen simplex chronicus, Pityriasis Rosea and pemphigus. Topical antihistaminic preparations currently available include 1% and 2% diphenhydramine (Benadryl® and Caladryl®), 5% doxepin (Zonalon®) cream, phiramine maleate, chlorpheniramine and tripeleminamine, phenothiazines, promethazine hydrochloride (Phenergan®) and dimethindene maleate. These drugs, as well as additional antihistamins can also be incorporated in the composition of the present invention.

It is pointed out that polyunsaturated fatty acids, containing omega-3 and omega-6 fatty acids (e.g., linoleic and linolenic acid, gamma-linoleic acid (GLA), eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) are beneficial in the treatment of psoriasis and other skin inflammation conditions. Thus in a preferred embodiment, a hair growth foam is provided, wherein the hydrophobic solvent comprises in full or in part, an oil, rich in such unsaturated fatty acids, thus, affording a synergistic therapeutic effect of the antiinflammatory agent and the vehicle components.

A second class of anti-inflammatory agents which is useful in the foam of the present invention includes the nonsteroidal anti-inflammatory agents (NSAIDs). The variety of compounds encompassed by this group are well-known to those skilled in the art. Specific non-steroidal anti-inflammatory agents useful in the composition invention include, but are not limited to:

- 1) Oxicams, such as piroxicam, isoxicam, tenoxicam, sudoxicam;
- 2) Salicylates, such as aspirin, disalcid, benorylate, trilisate, safapryn, solprin, diflunisal, and fendosal;
- 3) Acetic acid derivatives, such as diclofenac, fenclofenac, indomethacin, sulindac, tolmetin, isoxepac, furofenac, tiopinac, zidometacin, acematacin, fentiazac, zomepirac, clindanac, oxepinac, felbinac, and ketorolac;
- 4) Fenamates, such as mefenamic, meclofenamic, flufenamic, niflumic, and tolfenamic acids;
- 5) Propionic acid derivatives, such as ibuprofen, naproxen, benoxaprofen, flurbiprofen, ketoprofen, fenoprofen, fenbufen, indoprofen, piroprofen, carprofen, oxaprozin, pranoprofen, miroprofen, tiroxaprofen, suprofen, alminoprofen, and tiaprofenic; and



6) Pyrazoles, such as phenylbutazone, oxyphenbutazone, feprazone, azapropazone, and trimethazone.

Mixtures of these non-steroidal anti-inflammatory agents may also be employed, as well as the dermatologically acceptable salts and esters of these agents.

The pharmaceutical composition of the present invention may also comprise an antiinflammatory or antiallergic agent, wherein said agent reduces the occurrence of pro-inflammatory cytokines or inhibits the effect of pro-inflammatory cytokines.

Topical application of a foam, comprising a safe and effective dose of an NSAID can be useful in the alleviation of the symptoms of rheumatoid arthritis, osteoarthritis and pain. Topical NSAIDs, incorporated in the foam of the present invention can be also used in the treatment of dermatological disorders, such as acne, rosacea, hair growth disorders, actinic keratosis and certain skin cancer conditions.

### **Topical Anesthetics**

The compositions of the present invention may contain a safe and effective amount of a topical anesthetic. Examples of topical anesthetic drugs include benzocaine, lidocaine, bupivacaine, chlorprocaine, dibucaine, etidocaine, mepivacaine, tetracaine, dyclonine, hexylcaine, procaine, cocaine, ketamine, pramoxine, phenol, and pharmaceutically acceptable salts thereof.

### **Retinoids**

Another preferred group of active agents comprise retinol, all trans retinoic acid and derivatives, isomers and analogs thereof, collectively termed "retinoids". Compositions according to the present invention, which contain retinoids as the active drug, can be used for the treatment of acne, seborrhea, various dermatoses, inflammation of the skin, mucosal membranes, vagina and the rectum, psoriasis and cancers, by application onto the affected area.

### **Insecticide and Insect repellents agents**

Insects, such as mosquitoes, biting flies, mites, gnats, fleas, chiggers, punkies, sand flies, lice and ticks can be annoying and sometimes pose a serious risk to human and animal health. In certain areas of the United States, mosquitoes can transmit diseases like equine and St. Louis encephalitis. Biting flies can inflict a painful bite that can persist for days, swell, and become infected. Ticks can transmit serious diseases like Lyme disease and Rocky Mountain spotted fever.

There are several types of insect repellents to use when protecting people from flying or biting insects such as mosquitoes, ticks, and. By way of example, these may include DEET (N, N-diethyl-m-toluamide), dimethyl phthalate and permethrin. Insect repelling terpenoids, have been reported by Hwang, et al, J. Chem. Ecol., 11, 1297 (1985); and Ruledge, J. Am. Mosquito Control Assoc. 4, 414 (1988).

A particularly preferred group of insect repellents includes the terpenoid compounds, described in U.S. Patent No. 5,411,992, including:

(1) Terpenoid-alcohol or Terpene-ols are terpenoids which have at least one hydroxyl group. Examples of terpene-ols include:  $C_{10}H_{16}O$  compounds, perillyl alcohol, carveol, myrtenol, and cis-verbenol;  $C_{10}H_{18}O$  compounds, myrtenol, iso-pinocampheol, dihydrocarveol, isopulegol, terpeneol, terpinen-4-ol, nerol, geraniol, and linalool, and  $C_{10}H_{20}O$  compounds, menthol, beta-citronellol, and dihydro-myrcenol.

(2) Terpenoid-esters are terpenoids which have at least one ester group which is the product of the bonding of the hydroxyl group of a terpene-ol with an aliphatic carboxylic acid that can contain functional groups such as the hydroxyl or amine on the aliphatic chain. Examples of suitable aliphatic carboxylic acids include acetic acid, propionic acid, lactic acid, and various amino acids. Examples of terpenoid-esters include: carvyl acetate, carvyl propionate, and menthyl lactate.

(3) Essential oils which contain terpenoids and perfumes which contain terpenoids. Non-limiting examples of essential oils which have high content of terpene-ols and esters include bergamot (62% terpenoids); sage (>50% terpenoids); styrax (>50% terpenoids); peppermint (>50% terpenoids); and pine Siberian (75% terpenoids %). Terpenes, aldehydes and ketones vary in their usefulness but as a general group have potential as insect-repellent.

The foam of the present invention is particularly suitable for the effective uniform spreading of an insect repellent agent onto large areas of the skin of humans and animals. The hydrophobic solvent present in the foam composition helps retain the insect repellent on the skin surface for an extended period of time.

Yet, in a further embodiment, the foam is suitable for delivery of insect-killing agents (insecticides) to an afflicted external surface area of humans and animals. Thus, the pharmaceutical or cosmetic composition may comprise an insecticide, known in the art of parasitology. By way of example, such insecticide can be selected from the group of permethrin, hexachlorobenzene, carbamate, naturally occurring pyrethroids, permethrin, allethrin, malathion, piperonyl butoxide and any combination thereof at a therapeutically effective concentration. Its application is very convenient and it

spreads easily, even over hairy areas. The hydrophobic solvent present in the foam composition helps retain the insecticide on the treated area for an extended period of time. Furthermore, the presence of a hydrophobic solvent in the foam eases mechanical removal of lice and nits with a comb.

### **Anti cancer drugs**

Anti cancer drugs can also be used according to the present invention as the drug of choice from skin malignant tumors, such as basal cell carcinoma, squamous cell carcinoma, melanoma and Kaposi's sarcoma, as well as the pre-cancerous condition actinic keratosis. In certain cases, topical cytotoxic and antiproliferative drugs are used to treat or prevent such cancers, including 5-fluorouracil, also called 5-FU. 5-FU, as well as any other anti-cancer agents, known in the art of cancer medicine, can be incorporated in the foam at therapeutically effective levels.

A preferred family of anticancer drugs, suitable for usage in the foam of the present formulation comprises antiestrogens, such as tamoxifen. Tamoxifen blocks the effects of the hormone estrogen in the body. It is used to prevent or delay the return of breast cancer or to control its spread.

### **Photodynamic therapy agents**

The foam composition of the present invention is also useful to deliver photo-sensitizing agents, known in the art of photodynamic therapy. By way of example, such photosensitizers can be selected from the group comprising modified porphyrins, chlorins, bacteriochlorins, phthalocyanines, naphthalocyanines, pheophorbides, purpurins, m-THPC, mono-L-aspartyl chlorin e6, bacteriochlorins, phthalocyanines, benzoporphyrin derivatives, as well as photosensitizer precursors, such as aminolevulinic acid (ALA).

### **Active agents for burns, wounds, cuts and ulcers**

The treatment of burns, wounds, cuts and ulcers, using the composition of the present invention is particularly advantageous. The foam can include both anti-infective agents (against bacteria, fungi and/or viruses), antiinflammatory agents (steroidal and/or NSAIDs) and pain relieving components. Upon application, the foam spreads easily, covering the surface of the affected area, and without causing pain.

### **SKIN CARE ACTIVE AGENTS**

The foam of the present invention is useful and advantageous for skin care and cosmetic care. The combination of oil and water, having moisture-retaining properties, in a spreadable foam form, can be used to substitute currently used cosmetic skin care creams, lotions, gels, etc. The

cosmetic foam compositions of the present invention are suitable for the further application as "cosmeceutical" preparation (cosmetic products with therapeutic benefit), to treat "cosmetic" skin disorders, such as aging skin, wrinkles, hyperpigmentation (melasma, Chloasma, freckles, etc.), scaly skin and other skin undesirable properties.

The CTFA Cosmetic Ingredient Handbook describes a wide variety of nonlimiting cosmetic and pharmaceutical ingredients commonly used in the skin care industry, which are suitable for use in the compositions of the present invention. Examples of these ingredient classes include: abrasives, absorbents, aesthetic components such as fragrances, pigments, colorings/colorants, essential oils, astringents, etc. (e.g., clove oil, menthol, camphor, eucalyptus oil, eugenol, menthyl lactate, witch hazel distillate), anti-acne agents, anti-caking agents, antifoaming agents, antimicrobial agents (e.g., iodopropyl butylcarbamate), antioxidants, binders, biological additives, buffering agents, bulking agents, chelating agents, chemical additives, colorants, cosmetic astringents, cosmetic biocides, denaturants, drug astringents, external analgesics, film formers or materials, e.g., polymers, for aiding the film-forming properties and substantivity of the composition (e.g., copolymer of eicosene and vinyl pyrrolidone), opacifying agents, pH adjusters, propellants, reducing agents, sequestrants, skin bleaching and lightening agents (e.g., hydroquinone, kojic acid, ascorbic acid, magnesium ascorbyl phosphate, ascorbyl glucosamine), skin-conditioning agents (e.g., humectants, including miscellaneous and occlusive), skin soothing and/or healing agents (e.g., panthenol and derivatives (e.g., ethyl panthenol), aloe vera, pantothenic acid and its derivatives, allantoin, bisabolol, and dipotassium glycyrrhizinate), skin treating agents, thickeners, and vitamins and derivatives thereof.

In any embodiment of the present invention, however, the active agents useful herein can be categorized by the benefit they provide or by their postulated mode of action. It is to be understood that the active agents useful herein can in some instances provide more than one benefit or operate via more than one mode of action. Therefore, classifications herein are made for the sake of convenience and are not intended to limit the active to that particular application or applications listed.

#### **Anti-acne active agents**

The compositions of the present invention may contain a safe and effective amount of one or more anti-acne active agents. Examples of useful anti-acne actives include resorcinol, sulfur, salicylic acid, benzoyl peroxide, retinoic acid, adapalene, azelaic acid and azelaic acid derivatives, antibiotic agents, such as erythromycin, zinc, etc., and combinations thereof.

#### **Anti-wrinkle active agents/anti-atrophy active agents**

The compositions of the present invention may further contain a safe and effective amount of one or more anti-wrinkle actives or anti-atrophy actives, which can be easily delivered by spreading a foam onto the skin. Exemplary anti-wrinkle/anti-atrophy active agents suitable for use in the compositions of the present invention include sulfur-containing D and L amino acids and their derivatives and salts, particularly the N-acetyl derivatives; thiols; hydroxy acids (e.g., alpha-hydroxy acids such as lactic acid and glycolic acid or beta-hydroxy acids such as salicylic acid and salicylic acid derivatives such as the octanoyl derivative), phytic acid, lipoic acid; lysophosphatidic acid, skin peel agents (e.g., phenol and the like), vitamin B3 compounds (e.g., nicotinic acid esters, including non-vasodilating esters of nicotinic acid (such as tocopheryl nicotinate), nicotinyl amino acids, nicotinyl alcohol esters of carboxylic acids, nicotinic acid N-oxide and niacinamide N-oxide) and retinoids (e.g., retinol, retinal, retinoic acid, retinyl acetate, retinyl palmitate, retinyl ascorbate).

#### **Anti-oxidants/radical scavengers**

A safe and effective amount of an anti-oxidant/radical scavenger may be added to the compositions of the subject invention, preferably from about 0.1% to about 10%, more preferably from about 1% to about 5%, of the composition.

Anti-oxidants/radical scavengers such as ascorbic acid (vitamin C) and its salts, ascorbyl esters of fatty acids, ascorbic acid derivatives (e.g., magnesium ascorbyl phosphate, sodium ascorbyl phosphate, ascorbyl sorbate), tocopherol (vitamin E), tocopherol sorbate, tocopherol acetate, other esters of tocopherol, butylated hydroxy benzoic acids and their salts, 6-hydroxy-2,5,7,8-tetramethylchroman-2-carboxylic acid (commercially available under the tradename Trolox<sup>sup</sup>.R), gallic acid and its alkyl esters, especially propyl gallate, uric acid and its salts and alkyl esters, sorbic acid and its salts, lipoic acid, amines (e.g., N,N-diethylhydroxylamine, amino-guanidine), sulfhydryl compounds (e.g., glutathione), dihydroxy fumaric acid and its salts, lysine pidolate, arginine pilolate, nordihydroguaiaretic acid, bioflavonoids, curcumin, lysine, methionine, proline, superoxide dismutase, silymarin, tea extracts, grape skin/seed extracts, melanin, and rosemary extracts may be used.

The foam of the present invention is suitable for delivering skin protecting and revitalizing anti-oxidants/radical scavengers. It is further pointed out that polyunsaturated fatty acids, containing omega-3 and omega-6 fatty acids (e.g., linoleic and linolenic acid, gamma-linoleic acid (GLA), eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) are beneficial in the treatment of psoriasis and other skin inflammation conditions. Likewise, emollients and silicone oils exert moisture-retaining and skin protective effects on the skin. Thus in a preferred embodiment, a skin protective foam is provided, wherein the hydrophobic solvent comprises in full or in part, a solvent, selected from the group of emollients, silicone oil and oils, rich in unsaturated fatty acids, thus,

affording a synergistic therapeutic effect of the anti-oxidants/radical scavenger agent and the vehicle components.

### **Tanning active agents**

The foam of the present invention is particularly suitable for the uniform delivery of a tanning active agent onto large areas of the skin. It is preferable that the compositions contain from about 0.1% to about 20%, more preferably from about 2% to about 7%, and still more preferably from about 3% to about 6%, by weight of the composition, of dihydroxyacetone, or any other compound, known in the art as an artificial tanning active agent.

### **Skin Lightening Agents**

The foam of the present invention is particularly suitable for the uniform delivery of a skin lightening agent. When used, the compositions preferably contain from about 0.1% to about 10%, more preferably from about 0.2% to about 5%, by weight of the composition, of a skin lightening agent. Suitable skin lightening agents include those known in the art, including kojic acid, arbutin, nicotinic acid and derivatives thereof, ascorbic acid and derivatives thereof (e.g., magnesium ascorbyl phosphate or sodium ascorbyl phosphate), and extracts (e.g., mulberry extract, placental extract).

### **Sunscreens**

Exposure to ultraviolet light can result in excessive scaling and texture changes of the stratum corneum. The foam of the present invention is advantageous for the delivery of sunscreen agents. Its application is very convenient and it spreads easily over large skin areas. The presence of a hydrophobic solvent in the foam ensures long lasting effect, even while bathing.

As used herein, "*sunscreen active*" includes both *sunscreen* agents and physical sunblocks. Suitable *sunscreen* actives may be organic or inorganic.

Inorganic sunscreens useful herein include the following metallic oxides; titanium dioxide having an average primary particle size of from about 15 nm to about 100 nm, zinc oxide having an average primary particle size of from about 15 nm to about 150 nm, zirconium oxide having an average primary particle size of from about 15 nm to about 150 nm, iron oxide having an average primary particle size of from about 15 nm to about 500 nm, and mixtures thereof. When used herein, the inorganic sunscreens are present in the amount of from about 0.1% to about 20%, preferably from about 0.5% to about 10%, more preferably from about 1% to about 5%, by weight of the composition.

A wide variety of conventional organic *sunscreen* actives are suitable for use herein. Specific suitable *sunscreen* actives include, for example:

p-aminobenzoic acid, its salts and its derivatives (ethyl, isobutyl, glyceryl esters; p-dimethylaminobenzoic acid); anthranilates (i.e., o-amino-benzoates; methyl, menthyl, phenyl, benzyl, phenylethyl, linalyl, terpinyl, and cyclohexenyl esters); salicylates (amyl, phenyl, octyl, benzyl, menthyl, glyceryl, and di-pro-pyleneglycol esters); cinnamic acid derivatives (menthyl and benzyl esters, a-phenyl cinnamionitrile; butyl cinnamoyl pyruvate); dihydroxycinnamic acid derivatives (umbelliferone, methylumbelliferone, methylaceto-umbelliferone); trihydroxy-cinnamic acid derivatives (esculetin, methylesculetin, daphnetin, and the glucosides, esculin and daphnin); hydrocarbons (diphenylbutadiene, stilbene); dibenzalacetone and benzalacetophenone; naphtholsulfonates (sodium salts of 2-naphthol-3,6-disulfonic and of 2-naphthol-6,8-disulfonic acids); di-hydroxynaphthoic acid and its salts; o- and p-hydroxybiphenyldisulfonates; coumarin derivatives (7-hydroxy, 7-methyl, 3-phenyl); diazoles (2-acetyl-3-bromoindazole, phenyl benzoxazole, methyl naphthoxazole, various aryl benzothiazoles); quinine salts (bisulfate, sulfate, chloride, oleate, and tannate); quinoline derivatives (8-hydroxyquinoline salts, 2-phenylquinoline); hydroxy- or methoxy-substituted benzophenones; uric and violuric acids; tannic acid and its derivatives (e.g., hexaethylether); (butyl carboto) (6-propyl piperonyl) ether; hydroquinone; benzophenones (oxybenzene, sulisobenzene, dioxybenzene, benzoescorcinol, 2,2',4,4'-tetrahydroxybenzophenone, 2,2'-dihydroxy-4,4'-dimethoxybenzophenone, octabenzene; 4-isopropylidibenzoylmethane; butylmethoxydibenzoylmethane; etocrylene; octocrylene; [3-(4'-methylbenzylidene bornan-2-one), terephthalylidene dicamphor sulfonic acid and 4-isopropyl-di-benzoylmethane.

A safe and effective amount of the organic sunscreen active is used, typically from about 1% to about 20%, more typically from about 2% to about 10% by weight of the composition. Exact amounts will vary depending upon the sunscreen or sunscreens chosen and the desired Sun Protection Factor (SPF).

### **Agents for hair growth disorders**

Agents, which affect the pattern of hair growth, can be suitably incorporated in the foam of the present invention. Male pattern baldness (MPB), the commonest cause of balding, is induced by the activity of the male hormone dihydrotestosterone (DHT) which converted from the hormone testosterone by the enzymes 5 alpha reductase. Current treatments of MPB include minoxidil and agents which inhibit 5 alpha reductase, such as finasteride, spironolactone, azelaic acid and azelaic acid derivatives and salts. Such agents, as well as other agents known in the art, can be incorporated in the foam of the present invention.

It is further pointed out that polyunsaturated fatty acids, i.e., such which include any of the essential fatty acids (EFA's): linoleic and linolenic acid, gamma-linoleic acid (GLA), eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), are also known to contribute to hair growth. Thus in a preferred

embodiment, a hair growth foam is provided, wherein the hydrophobic solvent comprises in full or in part, an oil, rich in such unsaturated fatty acids.

### **Figur-forming Agents; Agents to Treat Cellulite / Slimming**

Figur forming agents such as used in the treatment of cellulite and in slimming products, can be suitably incorporated in the foam of the present invention. Following is a non-limiting list of active agents, known in the treatment of cellulite and in the induction of a slimming effect:

- Herbal extracts: baldderwack extract, butcher's, broom, cayenne, dandelion, red clover, ginkgo biloba, horse chestnut, witch hazel and borage oil
- Omega 3 and omega 6 oils
- Caffeic acid

### **Agents to treat sunburn, heat burn, radiation burn, rash and itch**

Cosmeic ingredients which are known in the art of pharmacology and cosmetology to treat dermatitis, minor skin irritations, sunburn, heat burn, radiation burn, and inhibit inflammation can be beneficially incorporated in the foam of the present invention.

Examples of such active agents include chamomile extract (*Matricaria recutitia*), cucumber distillate (*Cucumis sativus*), lavender water (*Lavendula Angustifolia*), rose water (*Rosa damascena*), witch hazel (*Hamamelis virginiana*), allantoin, bisabolol, rosehip oil, calendula oil, azulene, menthol and camphor.

### **Use of the Foam as a Lubricating and Protective Foam**

There are several potential uses of the foam, particularly the silicone-oil based foam, as a lubricating foam. Typical examples are shaving foam, moisture protection foam and antifriction foam. For such purposes, the foam can be used in its basic composition (without additional formulation aids and active ingredients), or with the addition of such additives.

### **FOAM FOR NEUTRALIZATION OF HAZARDOUS CHEMICALS AND TREATMENT OF HEAT BURNS**

It has been reported that povidone iodine antiseptic, a popular iodine product can ameliorate damage to guinea pig skin exposed to mustard gas and other chemical irritants and further reduces, and many times prevents, damage to human skin after accidental heat burns caused by hot water, oil or hot steam.

Other active compound, having decontamination abilities, comprise strong oxidants and free radical liberating compounds, such as hydrogen oxide,



bleaching agents (e.g., sodium, calcium or magnesium hypochloride and the like) iodine, chlorohexidine and benzoyl peroxide.

An alcohol-free foam of the present invention, comprising one or more of the above decontaminating and neutralizing agents can be applied onto the contaminated skin to form a preventive layer, prior to contamination measure or as a decontamination/neutralization means, right after contamination has occurred.

#### **FURTHER TECHNICAL PARAMETERS**

The composition of the present invention may be contained in and dispensed from a container capable of withstanding the pressure of the propellant gas and having an appropriate valve/nozzle for dispensing the composition as foam under pressure. A customary propellant can be added, in the amount of about 5-25% by weight of the total composition.

A specific embodiment according to the present invention comprises placing the composition of the present invention on a patch, occlusive tape or the skin-contact compartment of a transdermal delivery apparatus and applying such object onto the skin, in order to attain effective superficial treatment or enhanced penetration of the drug into the skin or through the skin.

Utilizing such strategy, one can apply drugs, which are currently administered systemically or that require transdermal delivery, in the preferred therapeutic system of the present invention. Examples for such drugs are nicotine, testosterone and other male hormones and male hormone precursors, estrogen and other female hormones and hormone precursors, growth hormone, insulin, caffeine, steroidal and non-steroidal antiinflammatory agents and thyroid hormone substitutes.

The general process, as typically exemplified in Example 1 may be applied in order to produce the composition of the present invention. The pharmaceutical carrier according to the present invention can also be used to prepare cosmetics for beauty purpose by adding into skin care agents and perfume.

## EXAMPLES

In the following, we are going to describe some examples and experiments in detail. This invention is not limited to these examples and experiments. Many variations will suggest themselves are within the full intended scope of the appended claims.

### **Example 1 – Production of Pharmaceutical or Cosmetic Foam Carrier and composition – General Method**

The method for preparing of a pharmaceutical foam carrier generally comprised following steps.

#### Ingredients:

- hydrophobic solvent: 25-75% by weight
- water: 25-80% by weight
- foam adjuvant agent: 0.1% to 5% by weight
- surface active agent: 0.1% to 5% by weight
- water gelling agent: 0.1% to 5% by weight

#### Procedure:

Aqueous Phase: Water gelling agent and surface active agent are dissolved in water, with agitation. The solution is warmed to 50-80°C. Water soluble Cosmetic or Pharmaceutical Active Ingredients\* and optional water soluble ingredients are added with agitation to the Aqueous Phase mixture.

Hydrophobic Phase: The hydrophobic solvent is heated to same temperature. Foam adjuvant agent is added to preheated hydrophobic solvent. Oil soluble Cosmetic or Pharmaceutical Active Ingredients\* and optional oil soluble formulation ingredients are added with agitation to the Hydrophobic Phase mixture.

The warm Hydrophobic Phase is gradually poured into the warm Aqueous Phase, with agitation, followed by Ultraturax homogenization. The mixture is allowed to cool down to ambient temperature.

The mixture, at ambient temperature, is added to an aerosol container, the container is sealed and appropriate amount of propellant (about 10% of the composition mass) is compressed into the container.

\* in case of heat sensitive Active Ingredients, add the Active Ingredient with agitation to the mixture, after Step 3.

### Example 2 – Vegetable Oil-Based Foam Carrier Composition

	Ingredient	Version No. 1	Version No. 2	Version No. 3
		% (W/W)		
Hydrophobic solvent	Soybean oil	50	64.5	37
Water	Water	48.5	32.5	61
Foam adjuvant agent	Stearyl Alcohol	0.8	1.05	0.73
Surface active agent	Sucrose ester SP70	0.64	0.45	0.8
Water gelling agent	Xanthan Gum	0.16	0.11	0.1
	Methocel ELV15	0.32	0.22	0.28
Other Ingredients	Antioxidant	0.02	0.02	0.02
	Preservatives	1	1	1
	Fragrance	0.2	0.2	0.2
Foam Specific gravity (gr/mL)		0.10	0.15	0.065

The foam of this example is useful as a carrier of active pharmaceutical and/or cosmetic active ingredients, as exemplified below. It also can be used as a protective product. Additionally, it is also useful as lubricating foam, for various purposes.

### Example 3 – Silicone Oil-Based Foam Carrier Composition

	Specific Ingredient	Version No. 1	Version No. 2
		% (W/W)	
Hydrophobic solvent	Silicone oil 350	25	25
Water	Water	72	72
Foam adjuvant agent	Stearyl Alcohol	0.2	0.2
Surface active agent	Sucrose ester SP70	0.8	-
	Myrj 49P	-	0.8
Water gelling agent	Xanthan Gum	0.2	0.2
	Methocel ELV15	0.4	0.4
Other Ingredients	Antioxidant	0.02	0.02
	Preservatives	1	1
	Fragrance	0.2	0.2
Foam Specific gravity (gr/mL)		0.10	ND

The foam of this example is useful as a carrier of active pharmaceutical and/or cosmetic active ingredients, as exemplified below. It also can be used as a protective product. Additionally, it is also useful as lubricating foam, for various purposes.

#### Example 4 – Palm Oil-Based Foam Carrier Composition

	Ingredient	Version No. 1	Version No. 2	Version No. 3	Version No. 4	Version No. 5
		% (W/W)				
Hydrophobic solvent	Palm Olein	48	48	48	64.5	64.5
Water	Water	47.66	49.26	48.46	31.91	32.91
Foam adjuvant agent	Stearyl Alcohol	1.6	-	0.8	1.0	-
Surface active agent	Sucrose ester SP70	0.64	0.64	0.64	0.64	0.64
Water gelling agent	Xanthan Gum	0.16	0.16	0.16	0.11	0.11
	Methocel ELV15	0.32	0.32	0.32	0.22	0.22
Other Ingredients	Antioxidant	0.02	0.02	0.02	0.02	0.02
	Preservatives	1	1	1	1	1
	Fragrance	0.2	0.2	0.2	0.2	0.2
Foam Specific gravity (gr/mL)		ND	ND	ND	ND	ND

The foam of this example is useful as a carrier of active pharmaceutical and/or cosmetic active ingredients, as exemplified below. It also can be used as a protective product.

#### Example 5 – Rosehip Oil-Based Foam Carrier Composition

	Ingredient	Version No. 1	Version No. 2	Version No. 3	Version No. 4	Version No. 5
		% (W/W)				
Hydrophobic solvent	Rose hip oil	50	50	37	25	25
Water		46.72	46.48	59.45	71.68	71.8
Foam adjuvant agent	Stearyl Alcohol	1	1	0.73	0.5	0
	Behenyl alcohol	-	-	-	-	0.5
Surface active agent	Sistema sucrose ester SP70	0.64	0.64	0.8	0.8	0.8
Water gelling agent	Xanthan Gum	0	0.14	0.17	0.2	0.16
	Methocel ELV15	0.22	0.32	0.43	0.4	0.32
Other Ingredients	Antioxidant	0.02	0.02	0.02	0.02	0.02
	Preservatives	1	1	1	1	1
	Fragrance	0.2	0.2	0.2	0.2	0.2
Foam Specific gravity (gr/mL)		0.08	ND	ND	0.05	ND

The foam of this example is useful as a carrier of active pharmaceutical and/or cosmetic active ingredients, as exemplified below. It also can be used as is, in the treatment of ageing skin, wrinkles, scars and pigmentation disorders, due to the biological effectiveness of rosehip oil.

#### Example 6 – Mineral Oil-Based Foam Carrier Composition

	Ingredient	Version No. 1	Version No. 2	Version No. 3	Version No. 4	Version No. 5
		% (W/W)				
Hydrophobic solvent	Mineral oil	69	50	50	25	25
Water	Water	28.4	46.7	46.7	71.88	71.9
Foam adjuvant agent	Stearyl Alcohol	0.7	1	1	0.5	0.5
Surface active agent	Sucrose ester SP70	0.4	0.64	0	0.8	0
	PEG S-40	0	0	0.64	0	0
	Polysorbate-60	0	0	0	0	0.8
Water gelling agent	Xanthan Gum	0.1	0	0.14	0.2	0.2
	Methocel ELV15	0.2	0.4	0.32	0.4	0.4
Other Ingredients	Antioxidant	0.02	0.02	0.02	0.02	0.02
	Preservatives	1	1	1	1	1
	Fragrance	0.2	0.2	0.2	0.2	0.2
Foam Specific gravity (gr/mL)		ND	ND	ND	ND	0.1

The foam of this example is useful as a carrier of active pharmaceutical and/or cosmetic active ingredients, as exemplified in examples below. It is also useful as lubricating foam, for various purposes.

### Example 7 – Antibacterial Foam Composition

Ingredient	Version 1 "Mupirocin"	Version 2 "Triple Antibiotic"	Version 3 "Fucidic Acid"	Version 4 "MetroFoam"
<b>Carrier Ingredients</b>				
Mineral oil	48.8%	48.8%	48.8%	48.8%
Stearyl Alcohol	0.8%	0.8%	0.8%	0.8%
Water	50%	50%	50%	50%
Xanthan Gum	0.2%	0.2%	0.2%	0.2%
Methocel ELV15	0.2%	0.2%	0.2%	0.2%
<b>Active Ingredients</b>				
Mupirocin	2%			
Polymyxin B Sulfate		10,000 Units/gr		
Bacitracin Zinc		500 Units/gr		
Neomycin Sulfate*		0.05%		
Pramoxine HCl		1%		
Fucidic acid			2%	
Metronidazole				1%

The foam of this example is useful for the treatment of the following medical indications:

- Bacterial skin infection (general)
- Cellulitis
- Open wounds
- Cutaneous abscesses
- Furuncles
- Insect bite
- Impetigo
- Acne
- Acne-rosacea
- Trichomonas vaginitis

In certain embodiments, the foam of this example is useful for the prevention, decontamination and/or neutralization hazardous bacterial infestation (such as warfare organisms)

### Example 8 – Antifungal Foam Composition

Ingredient	Version 1 "Terbinafine"	Version 2 "Triple Antibiotic"	Version 3 "Nystatin"
<b>Carrier Ingredients</b>			
Mineral oil	48.8%	48.8%	48.8%
Stearyl Alcohol	0.8%	0.8%	0.8%
Water	50%	50%	50%
Xanthan Gum	0.2%	0.2%	0.2%
Methocel ELV15	0.2%	0.2%	0.2%
<b>Active Ingredients</b>			
Terbinafine	1%		
clotrimazole		2%	
Nystatin			100,000 Units/gr

#### Indications:

- Dermatophyte Infections
  - o Tinea corporis
  - o Tinea pedis
  - o Tinea rubrum
  - o Tinea unguium
  - o Tinea cruris
  - o Tinea barbae
- Yeast Infections
  - o Candidiasis
  - o Tinea versicolor
  - o Candidal vaginitis

### Example 9 – Corticosteroid Foam Composition

Ingredient	Version 1 "Hydrocortisone"	Version 2 "Betamethasone"	Version 3 "Dexamethasone"
<b>Carrier Ingredients</b>			
Mineral oil	48.8%	48.8%	48.8%
Stearyl Alcohol	0.8%	0.8%	0.8%
Water	50%	50%	50%
Xanthan Gum	0.2%	0.2%	0.2%
Methocel ELV15	0.2%	0.2%	0.2%
<b>Active Ingredients</b>			
Hydrocortisone	1%		
Betamethasone dipropionate		0.05%	
Dexamethasone acetate			0.1%

Ingredient	Version 4 "Triamcinolone"	Version 5 "Flumetasone"
<b>Carrier Ingredients</b>		
Mineral oil	48.8%	48.8%
Stearyl Alcohol	0.8%	0.8%
Water	50%	50%
Xanthan Gum	0.2%	0.2%
Methocel ELV15	0.2%	0.2%
<b>Active Ingredients</b>		
Triamcinolone acetonide	0.1%	
Flumetasone pivalate		0.02%

#### Indications:

- Psoriasis
- Contact dermatitis
- Atopic dermatitis
- Seborrheic dermatitis
- Nummular dermatitis
- Inflammatory acne
- Chronic dermatitis of the hands and feet
- Generalized exfoliative dermatitis
- Stasis dermatitis
- Lichen simplex chronicus
- Herpes gestationis
- Pruritic urticarial papules and plaques of pregnancy



### Example 10 – Antiviral Foam Composition

Ingredient	Version 1 "Acyclovir"	Version 2 "α-Interferon"
<b>Carrier Ingredients</b>		
Mineral oil	48.8%	48.8%
Stearyl Alcohol	0.8%	0.8%
Water	50%	50%
Xanthan Gum	0.2%	0.2%
Methocel ELV15	0.2%	0.2%
<b>Active Ingredients</b>		
Acyclovir	5%	
α-Interferon		105 IU/g

#### Indications:

- Herpes simplex
- Herpes zoster
- Herpes gestationis
- Herpes simplex genital ulcers

### Example 11 – Sunscreen Foam Composition

Ingredient	%
<b>Carrier Ingredients</b>	
Mineral oil	48.8%
Stearyl Alcohol	0.8%
Water	50%
Xanthan Gum	0.2%
Methocel ELV15	0.2%
<b>Active Ingredients</b>	
titanium dioxide	3%
oxybenzone	5%
ethylhexyl-p-methoxycinnamate	7.5%
butylmethoxy-dibenzoylmethane	1.5%

### Example 12 – Comparative Acceptability Study of a Corticosteroid Composition Vs. a Conventional Ointment

A panel of eight testers was requested to apply about 0.5 gr. of the foam preparation of example 9, Version 2 on one arm and 0.5 gr. of commercial Betamethasone valerate ointment, in a double blind fashion. They were asked to describe their feeling about the ease of application, ease of spreading, spreadability and penetrability of each of the products and to give their general

rating for each of the products on a scale of 0-3 (0 = poor; 1=barely acceptable; 2=acceptable and 3=excellent).

As demonstrated in the following table, the foam preparation of example 9, Version 2 obtained higher rates in all aspects of the test.

Property	Foam Preparation	Commercial Betamethasone Valerate Ointment
	Mean Rating	Mean Rating
Ease of application	2.3	1.6
Ease of spreading	2.5	1.9
Spreadability	2.9	1.2
Penetrability	2.0	1.5
Lack of sticky feeling	2.4	1.0
Lack of greasy feeling	2.2	1.0
Lack of shiny look	1.9	1.4
Overall rating	2.5	1.4

## CLAIMS

1. An alcohol-free pharmaceutical or cosmetic foam carrier, comprising
  - hydrophobic solvent: 25-75% by weight
  - water: 25-75% by weight
  - foam adjuvant agent: 0.1% to 5% by weight
  - surface active agent: 0.1% to 5% by weight
  - water gelling agent: 0.1% to 5% by weight
2. An alcohol-free silicone based foam carrier, comprising
  - hydrophobic solvent: 7.5-50% by weight, wherein at least 7.5% is a silicone oil
  - water: 50-90% by weight
  - foam adjuvant agent: 0.1% to 5% by weight
  - surface active agent: 0.1% to 5% by weight
  - water gelling agent: 0.1% to 5% by weight
3. A pharmaceutical composition, comprising an alcohol-free pharmaceutical or cosmetic foam carrier, according to claim 1 or 2 and a therapeutically effective concentration of an active pharmaceutical ingredient.
4. A cosmetic composition, comprising an alcohol-free pharmaceutical or cosmetic foam carrier, according to claim 1 or 2 and a cosmetically effective agent.
5. The pharmaceutical or cosmetic foam carrier of claim 1 or 2, wherein the hydrophobic solvent is selected from vegetable oils, marine oils, mineral oils, silicone oils, plant-derived therapeutic oils and mixture thereof at any proportion.
6. The pharmaceutical or cosmetic composition of claim 1, 2, 3 or 4, wherein the hydrophobic solvent is selected from vegetable oils, marine oils, mineral oils, silicone oils, plant-derived therapeutic oils and mixture thereof at any proportion.
7. The pharmaceutical or cosmetic carrier or composition of claim 1, 2, 3 or 4, wherein said foam adjuvant agent has intrinsic anti infectious, anti viral or anti-inflammatory therapeutic properties.
8. The pharmaceutical or cosmetic carrier or composition of claim 1, 2, 3 or 4, further comprising pharmaceutical excipients, selected from the group consisting of water, surfactants, emulsifiers, diglycerides, triglycerides, stabilizing agents, antioxidants, glycerol, polymeric gelling agents, flavoring, colorant and odorant agents.

9. The carrier or composition of claim 1, 2 or 4, also comprising at least one drug.
10. The pharmaceutical composition of claim 3 wherein the drug is intended for the treatment of a disease, the etiology of which is bacterial, fungal, viral, parasitic, inflammatory, autoimmune, allergic, hormonal, malignant and combinations thereof.
11. The composition of claim 3 or 4 wherein the drug is intended for the treatment of a superficial condition.
12. The composition of claim 3 or 4 wherein the drug is intended for the treatment of a disorder of the skin, mucosal membrane, vagina and rectum.
13. The composition of claim 3 or 4 wherein the drug is intended for the treatment of disorders selected from the group of acne, seborrhea, seborrheic dermatitis, alopecia and excessive hair growth.
14. The composition of claim 3 or 4 wherein the drug is intended for the treatment of wounds, burns cuts and ulcers.
15. The composition of claim 3 wherein the drug is antibacterial.
16. The pharmaceutical composition of claim 15 wherein the drug is antibacterial, selected from the group of chloramphenicol, tetracyclines, synthetic and semi-synthetic penicillins, beta-lactams, quinolones, fluoroquinolones, macrolide antibiotics, peptide antibiotics, cyclosporines, free radical generating agents, iodine, chlorohexidine, benzoyl peroxide and any combination thereof at a therapeutically effective concentration.
17. The composition of claim 3 or 4 wherein the drug is antifungal.
18. The pharmaceutical composition of claim 17 wherein the antifungal drug is active against dermatophytes.
19. The pharmaceutical composition of claim 17 wherein the antifungal drug is active against candida.
20. The pharmaceutical composition of claim 17 wherein the antifungal drug is selected from the group of azoles, diazoles, triazoles, miconazole, fluconazole, ketoconazole, clotrimazole, itraconazole, griseofulvin, ciclopirox, amorolfine, terbinafine, Amphotericin B, potassium iodide, flucytosine (5FC) and any combination thereof at a therapeutically effective concentration.
21. The composition of claim 3 or 4 wherein the drug is antiviral.

22. The pharmaceutical composition of claim 21 wherein the antiviral drug is selected from the group of Vidarabine, Acyclovir, Gancyclovir, Nucleoside-analog reverse transcriptase inhibitors [AZT (Zidovudine), ddI (Didanosine), ddC (Zalcitabine), d4T (Stavudine), 3TC (Lamivudine)], Non-nucleoside reverse transcriptase inhibitors (Nevirapine, Delavirdine), Protease Inhibitors (Saquinavir, Ritonavir, Indinavir, Nelfinavir), Ribavirin, Amantadine / Rimantadine, Interferons and any combination thereof at a therapeutically effective concentration.
23. The composition of claim 3 or 4 wherein the active agent is an insecticide.
24. The composition of claim 3 or 4 wherein the active agent is an insect repellent.
25. The pharmaceutical composition of claim 23 or 24 wherein the antiparasite drug is selected from the group of hexachlorobenzene, carbamatenaturally occurring pyrethroids, permethrin, allethrin, malathion, piperonyl butoxide, any terpenol and derivatives thereof; and any combination thereof at a therapeutically effective concentration.
26. The composition of claim 3 or 4, wherein the drug is an antiinflammaoty or antiallergic agent.
27. The pharmaceutical composition of claim 26 wherein the antiinflammaoty or antiallergic agent is selected from the group of corticosteroids, non-steroidal antiinflammatory drugs, anti-histamines, immunosuppressants and any combination thereof at a therapeutically effective concentration.
28. The pharmaceutical composition of claim 26 wherein the antiinflammaoty agent is selected from the group of clobetasol proprionate, halobetasol proprionate, betamethasone dipropionate, betamethasone valerate, fluocinolone acetonide, halcinonide, betamethasone valerate, fluocinolone acetonide, hydrocortisone valerate, triamcinolone acetonide, hydrocortisone and any combination thereof at a therapeutically effective concentration.
29. The pharmaceutical composition of claim 26 wherein the antiinflammaoty agent is a nonsteroidal antiinflammatory drug.
30. The pharmaceutical composition of claim 26 wherein the antiinflammaoty agent is selected from the group of oxicams, piroxicam, isoxicam, tenoxicam, sudoxicam; salicylates, aspirin, disalcid, benorylate, trilisate, safapryn, solprin, diflunisal, and fendosal; acetic acid derivatives, diclofenac, fenclofenac, indomethacin, sulindac, tolmetin, isoxepac, furofenac, tiopinac, zidometacin, acematacin, fentiazac, zomepirac, clindanac, oxepinac, felbinac, and ketorolac; fenamates, mefenamic, meclofenamic, flufenamic, niflumic, and tolfenamic acids; propionic acid derivatives, ibuprofen, naproxen, benoxaprofen, flurbiprofen, ketoprofen, fenoprofen, fenbufen, indoprofen, piroprofen, carprofen, oxaprozin,

pranoprofen, mioprofen, tioxaprofen, suprofen, alminoprofen, and tiaprofenic; pyrazoles, such as phenylbutazone, oxyphenbutazone, feprazone, azapropazone, and trimethazone.

31. The pharmaceutical composition of claim 26 wherein the antiallergic agent is selected from the group of diphenhydramine, doxepin, phrilamine maleate, chlorpheniramine and tripeleminamine, phenothiazines, promethazine hydrochloride, dimethindene maleate and any combination thereof at a therapeutically effective concentration.

30. The pharmaceutical composition of claim 25 wherein said antiinflammatory or antiallergic agent reduces the occurrence of pro-inflammatory cytokines or inhibits the effect of pro-inflammatory cytokines.

31. The pharmaceutical composition of claim 3 wherein the drug is an anticancer agent.

32. The pharmaceutical composition of claim 3 wherein the drug is a photodynamic therapy agent.

33. The composition of claim 3 or 4 wherein the drug is a local anesthetic.

34. The composition of claim 3 or 4 wherein the drug is intended for transdermal delivery.

35. The composition of claim 3 or 4 wherein the composition is placed on a patch, occlusive tape or the skin-contact compartment of a transdermal delivery apparatus and applied onto the skin.

36. The pharmaceutical or cosmetic carrier and composition of claim 1, 2, 3 or 4, also comprising a sunscreen agent.

37. The carrier and composition of claim 36, wherein the sunscreen agent is selected from the group of UVA and UVB absorber.

38. The pharmaceutical or cosmetic composition of claim 34, wherein the sunscreen agent is selected from the groups of para-aminobenzoic acid (PABA), PABA esters, salicylates, cinnamates, anthranilates, Butylmethoxy-dibenzoylmethane and the benzophenones.

39. A foam preparation for neutralization and decontamination of warfare or industrial chemical hazards, comprising an oxidizing agent.

40. A foam preparation for neutralization and decontamination of warfare or industrial chemical hazards, comprising a decontaminating agent, selected from

the group of iodine and iodine compounds, bleaching agents and surface active agents.

41. A foam preparation for neutralization and decontamination of warfare or industrial chemical hazards, comprising

- hydrophobic solvent: 25-75% by weight
- water: 25-75% by weight
- foam adjuvant agent: 0.1% to 5% by weight
- surface active agent: 0.1% to 5% by weight
- water gelling agent: 0.1% to 5% by weight

and further comprising an oxidizing agent.

42. A foam preparation for neutralization and decontamination of warfare or industrial chemical hazards, comprising

- hydrophobic solvent: 25-75% by weight
- water: 25-75% by weight
- foam adjuvant agent: 0.1% to 5% by weight
- surface active agent: 0.1% to 5% by weight
- water gelling agent: 0.1% to 5% by weight

and further comprising a decontaminating agent, selected from the group of iodine, bleaching agent and surface active agent.

43. An alcohol-free lubricating foam, comprising

- hydrophobic solvent: 25-75% by weight
- water: 25-75% by weight
- foam adjuvant agent: 0.1% to 5% by weight
- surface active agent: 0.1% to 5% by weight
- water gelling agent: 0.1% to 5% by weight

44. An alcohol-free silicone based lubricating foam, comprising

- hydrophobic solvent: 7.5-50% by weight, wherein at least 7.5% is a silicone oil
- water: 50-90% by weight
- foam adjuvant agent: 0.1% to 5% by weight
- surface active agent: 0.1% to 5% by weight
- water gelling agent: 0.1% to 5% by weight

45. A method of treating or preventing a dermatological disorder, comprising:

administering topically to a subject having said dermatological disorder a therapeutically effective amount of a composition comprising:

- hydrophobic solvent: 25-75% by weight
- water: 25-75% by weight
- foam adjuvant agent: 0.1% to 5% by weight
- surface active agent: 0.1% to 5% by weight
- water gelling agent: 0.1% to 5% by weight

and at least one active agent

46. A method of treating or preventing a dermatological disorder, comprising:

administering topically to a subject having said dermatological disorder a therapeutically effective amount of a composition comprising

- hydrophobic solvent: 7.5-50% by weight, wherein at least 7.5% is a silicone oil
- water: 50-90% by weight
- foam adjuvant agent: 0.1% to 5% by weight
- surface active agent: 0.1% to 5% by weight
- water gelling agent: 0.1% to 5% by weight

and at least one active agent

47. The method of claim 46 or 47, wherein said compound is applied topically to an affected area.

48. The method of claim 46 or 47, wherein said dermatological disorder comprises bacterial infection, fungal infection, viral infection, inflammation, psoriasis, dermatosis, allergy, burn, wound, cut, insect infestation or cancer.

49. A method of preventing skin cancer, comprising:

administering topically to a subject having said dermatological disorder a therapeutically effective amount of a composition comprising:

- hydrophobic solvent: 25-75% by weight
- water: 25-75% by weight
- foam adjuvant agent: 0.1% to 5% by weight
- surface active agent: 0.1% to 5% by weight
- water gelling agent: 0.1% to 5% by weight

and at least one sunscreen agent



50. A method of preventing skin cancer, comprising:

administering topically to a subject having said dermatological disorder a therapeutically effective amount of a composition comprising:

- hydrophobic solvent: 7.5-50% by weight, wherein at least 7.5% is a silicone oil
- water: 50-90% by weight
- foam adjuvant agent: 0.1% to 5% by weight
- surface active agent: 0.1% to 5% by weight
- water gelling agent: 0.1% to 5% by weight

and at least one sunscreen agent

51. The foam carrier of claim 1 and 2, wherein the surface active agent is selected from the groups of non ionic surfactants, cationic surfactants, amphoteric and zwitterionic surfactants.

52. The foam carrier of claim 1 and 2, wherein the surface active agent is non ionic.

53. The foam of claim 41 - 44, wherein the surface active agent is selected from the groups of non ionic surfactants, cationic surfactants, amphoteric and zwitterionic surfactants.

54. The foam of claim 41 - 44, wherein the surface active agent is non ionic.

55. The method of claim 45 and 46, wherein the surface active agent is selected from the groups of non ionic surfactants, cationic surfactants, amphoteric and zwitterionic surfactants.

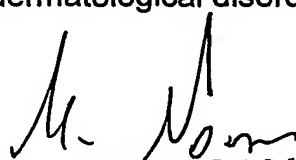
56. The method of claim 45 and 46, wherein the surface active agent is non ionic.

57. The composition of claim 1 and 2, having a specific gravity of 0.025 - 0.25 gr/mL, upon extrusion from a pressured container.

58. The lubricating foam of claim 43 - 44, for use as a shaving aid.

59. Use of the composition of claim 3 for treating a cosmetic disorder.

60. Use of the composition of claim 3 for treating a dermatological disorder.

  
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